

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: N.L. Haigwood

Attorney Docket No.: SBRI 122224/Haigwood
21nov03

Application No.: 10/719,004

Art Unit: 1653 / Confirmation No.: 9077

Filed: November 21, 2003

Examiner: J.S. Parkin

Title: AIDS VACCINES

INFORMATION DISCLOSURE STATEMENT

Seattle, Washington 98101

December 15, 2005

TO THE COMMISSIONER FOR PATENTS:

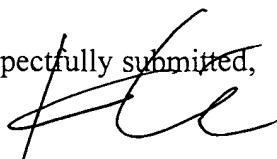
Applicant is aware of the information listed in the attached form that may be material to the prosecution of the above-identified patent application.

1. Copies of the listed non-patent literature are enclosed for the Examiner's use..

2. Pursuant to 37 C.F.R. § 1.97(b), this Information Disclosure Statement is being filed within three months of the filing date of the national application (other than a CPA), within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, before the mailing date of a first Office Action on the merits, or before the mailing date of a first Office Action after the filing of an RCE.

Seattle Biomedical Research Institute
307 Westlake Ave N Suite 500
Seattle, WA 98109-5219
206.256.7200

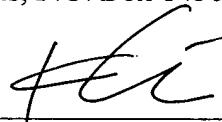
Respectfully submitted,



Karen Blöchliger, Ph.D.
Registration No. 41,395
Seattle Biomedical Research Institute
307 Westlake Ave N Suite 500
Seattle, WA 98109-5219
Telephone 206.256.7142

I hereby certify that this correspondence is being deposited with the U.S. Postal Service in a sealed envelope as first class mail with postage thereon fully prepaid and addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the below date.

Date: 12/15/05



Seattle Biomedical Research Institute
307 Westlake Ave N Suite 500
Seattle, WA 98109-5219
206.256.7200



INFORMATION CITED BY APPLICANTS THAT MAY BE MATERIAL TO THE
PROSECUTION OF THE SUBJECT APPLICATION

Applicants: N.L. Haigwood Attorney Docket No.: SBRI 122224/Haigwood
21nov03

Application No.: 10/719,004 Art Unit: 1653 / Confirmation No.: 9077

Filed: November 21, 2003 Examiner: J.S. Parkin

Title: AIDS VACCINES

U.S. PATENT DOCUMENTS

None

FOREIGN PATENT DOCUMENTS

None

OTHER INFORMATION
(Including Author, Title, Date, Pertinent Pages, Etc.)

*Examiner Cite
Initial No.

-
- _____ O1 Barnett, S.W., et al., "The Ability of an Oligomeric Human Immunodeficiency Virus Type 1 (HIV-1) Envelope Antigen to Elicit Neutralizing Antibodies Against Primary HIV-1 Isolates Is Improved Following Partial Deletion of the Second Hypervariable Region," *Journal of Virology* 75(12):5526-5540, June 2001.
- _____ O2 Barouch, D.H., et al., "Augmentation of Immune Responses to HIV-1 and Simian Immunodeficiency Virus DNA Vaccines by IL-2/Ig Plasmid Administration in Rhesus Monkeys," *Proceedings of the National Academy of Sciences* 97(8):4192-4197, April 2000.
- _____ O3 Binley, J.M., et al., "A Recombinant Human Immunodeficiency Virus Type 1 Envelope Glycoprotein Complex Stabilized by an Intermolecular Disulfide Bond Between the gp120 and gp41 Subunits Is an Antigenic Mimic of the Trimeric Virion-Associated Structure," *Journal of Virology* 74(2):627-643, January 2000.
- _____ O4 Brokstad, K.A., et al., "Cross-Reaction But No Avidity Change of the Serum Antibody Responses After Influenza Vaccination," *Vaccine* 13(16):1522-1528, 1995.

Seattle Biomedical Research Institute
306 Westlake Ave N Suite 500
Seattle, Washington 98109-5219
206.256.7200

- _____ O5 Burns, D.P., and R.C. Desrosiers, "Envelope Sequence Variation, Neutralizing Antibodies, and Primate Lentivirus Persistence," *Current Topics in Microbiology and Immunology* 188:185-219, 1994.
- _____ O6 Burns, D.P.W., et al., "Simian Immunodeficiency Virus Mutants Resistant to Serum Neutralization Arise During Persistent Infection of Rehsus Monkeys," *Journal of Virology* 67(7):4104-4113, July 1993.
- _____ O7 Burton, D.R., et al., "Efficient Neutralization of Primary Isolates of HIV-1 by a Recombinant Human Monoclonal Antibody," *Science* 266:1024-1027, November 1994.
- _____ O8 Cao, Y., et al., "Virologic and Immnologic Characterization of Long-Term Survivors of Human Immunodeficiency Virus Type 1 Infection," *New England Journal of Medicine* 332(4):201-208, Jan. 1995.
- _____ O9 Cecilia, D., et al., "A Longitudinal Study of Neutralizing Antibodies and Disease Progression in HIV-1-Infected Subjects," *Journal of Infectious Diseases* 179:1365-1374, 1999.
- _____ O10 Chackerian, B., et.al., "Specific N-Linked and O-Linked Glycosylation Modifications in the Envelope V1 Domain of Simian Immunodeficiency Virus Variants That Evolve in the Host Alter Recognition by Neutralizing Antibodies," *Journal of Virology* 71(10):7719-7727, October 1997.
- _____ O11 Chen, B. et al., "Structure of an Unliganded Simian Immunodeficiency Virus gp120 Core," *Nature* 433:834-841, February 2005.
- _____ O12 Cheng-Mayer, C., et al., "Selection for Neutralization Resistance of the Simian/Human Immunodeficiency Virus SHIV_{SF33A} Variant in Vivo by Virtue of Sequence Changes in the Extracellular Envelope Glycoprotein That Modify N-Linked Glycosylation," *Journal of Virology* 73(7):5294-5300, July 1999.
- _____ O13 Choisy, M., et al., "Comparative Study of Adaptive Molecular Evolution in Different Human Immunodeficiency Virus Groups and Subtypes, *Journal of Virology* 78(4):1962-1970, February 2004.
- _____ O14 Ciurea, A., et al., "Viral Persistence *In Vivo* Through Selection of Neutralizing Antibody-Escape Variants," *Proceedings of the National Academy of Sciences* 97(5):2749-2754, March 2000.
- _____ O15 Dacheux, L., et al., "Evolutionary Dynamics of the Glycan Shield of the Human Immunodeficiency Virus Envelope During Natural Infection and Implications For Exposure of the 2G12 Epitope," *Journal of Virology* 78(22):12625-12637, November 2004.

- _____ O16 D'Costa, S., et al., "Structural Features of HIV Envelope Defined by Antibody Escape Mutant Analysis," *AIDS Research and Human Retroviruses* 17(12):1205-1209, 2001.
- _____ O17 Dehghani, H., et al., "Unique Pattern of Convergent Envelope Evolution in Simian Immunodeficiency Virus-Infected Rapid Progressor Macaques: Association With CD4-Independent Usage of CCR5," *Journal of Virology* 77(11):6405-6418, June 2003
- _____ O18 Delwart, E.L., et al., "Slower Evolution of Human Immunodeficiency Virus Type 1 Quasispecies During Progression to AIDS," *Journal of Virology* 71(10):7498-7508, October 1997.
- _____ O19 Doria-Rose, N.A., and N.L. Haigwood, "DNA Vaccine Strategies: Candidates for Immune Modulation and Immunization Regimens," *Methods* 31:207-216, 2003.
- _____ O20 Doria-Rose, N.A., et al., "Multigene DNA Priming-Boosting Vaccines Protect Macaques From Acute CD4⁺-T-Cell Depletion After Simian-Human Immunodeficiency Virus SHIV89.6P Mucosal Challenge," *Journal of Virology* 77(21):11563-11577, November 2003
- _____ O21 Etemad-Moghadam, B., et al., "Characterization of Simian-Human Immunodeficiency Virus Envelope Glycoprotein Epitopes Recognized by Neutralizing Antibodies From Infected Monkeys, *Journal of Virology* 72(10):8437-8445, October 1998.
- _____ O22 Fouts, T., et al., "Crosslinked HIV-1 Envelope-CD4 Receptor Complexes Elicit Broadly Cross-Reactive Neutralizing Antibodies in Rhesus Macaques," *Proceedings of the National Academy of Sciences* 99(18):11842-11847, September 2002.
- _____ O23 Garrity, R.R., et al., "Refocusing Neutralizing Antibody Response by Targeted Dampening of an Immunodominant Epitope," *Journal of Immunology* 159:279-289, 1997.
- _____ O24 Geyer, H., et al., "Carbohydrates of Human Immunodeficiency Virus," *The Journal of Biological Chemistry*, 263(24):11760-11767, 1988
- _____ O25 Haigwood, N.L., et al., "Importance of Hypervariable Regions of HIV-1 gp120 in the Generation of Virus Neutralizing Antibodies," *AIDS Research and Human Retroviruses* 6(7):855-869, July 1990.

- _____ O26 Haigwood, N.L., et al., "Native But Not Denatured Recombinant Human Immunodeficiency Virus Type 1 gp120 Generates Broad-Spectrum Neutralizing Antibodies in Baboons," *Journal of Virology* 66(1):172-182, Jan. 1992.
- _____ O27 Hirsch, V.M., et al., "Viral Genetic Evolution in Macaques Infected With Molecularly Cloned Simian Immunodeficiency Virus Correlates With the Extent of Persistent Viremia," *Journal of Virology* 72(8):6482-6489, August 1998.
- _____ O28 Kimata, J.T., et al., "Emerging Cytopathic and Antigenic Simian Immunodeficiency Virus Variants Influence AIDS Progression," *Nature Medicine* 5(5):535-541, May 1999.
- _____ O29 Kimura, T., et al., "Reconstitution of Spontaneous Neutralizing Antibody Response Against Autologous Human Immunodeficiency Virus During Highly Active Antiretroviral Therapy," *Journal of Infectious Diseases* 185:53-60, 2002.
- _____ O30 Koch, M., et al., "Structure-Based, Targeted Deglycosylation of HIV-1 gp120 and Effects on Neutralization Sensitivity and Antibody Recognition," *Virology* 313:387-400, 2003.
- _____ O31 Kwong, P.D., et al., "Structure of an HIV-1 gp120 Envelope Glycoprotein in Complex with the CD4 Receptor and a Neutralizing Human Antibody," *Nature* 393:648-659, June 1998.
- _____ O32 Land, A., and I. Braakman, "Folding of the Human Immunodeficiency Virus Type 1 Envelope Glycoprotein in the Endoplasmic Reticulum," *Biochimie* 83:783-790, 2001.
- _____ O33 Leonard, C.K., et al., "Assignment of Intrachain Disulfide Bonds and Characterization of Potential Glycosylation Sites of the Type 1 Recombinant Human Immunodeficiency Virus Envelope Glycoprotein (gp120) Expressed in Chinese Hamster Ovary Cells," *Journal of Biological Chemistry* 265(18):10373-10382, June 1990.
- _____ O34 Ljungberg, K., et al., "Enhanced Immune Responses After DNA Vaccination With Combined Envelope Genes From Different HIV-1 Subtypes," *Virology* 302:44-57, 2002.
- _____ O35 Long, E.M., et al., "HIV Type 1 Variants Transmitted to Women in Kenya Require the CCR5 Coreceptor for Entry, Regardless of the Genetic Complexity of the Infecting Virus," *AIDS Research and Human Retroviruses* 18(8):567-576, 2002.

- _____ O36 Ly, A., and L. Stamatatos, "V2 Loop Glycosylation of the Human Immunodeficiency Virus Type 1 SF162 Envelope Facilitates Interaction of This Protein with CD4 and CCR5 Receptors and Protects the Virus From Neutralization by Anti-V3 Loop and Anti-CD4 Binding Site Antibodies," *Journal of Virology* 74(15):6769-6776, August 2000.
- _____ O37 Mascola, J.R., et al., "Immunization With Envelope Subunit Vaccine Products Elicits Neutralizing Antibodies Against Laboratory-Adapted But Not Primary Isolates of Human Immunodeficiency Virus Type 1," *Journal of Infectious Diseases* 173:340-348, 1996.
- _____ O38 McCaffrey, R.A., et al., "N-Linked Glycosylation of the V3 Loop and Immunologically Silent Face of gp120 Protects Human Immunodeficiency Virus Type 1 SF162 From Neutralization by Anti-gp120 and Anti-gp41 Antibodies," *Journal of Virology* 78(7):3279-3295, April 2004.
- _____ O39 Moog, C., et al., "Autologous and Heterologous Neutralizing Antibody Responses Following Initial Seroconversion in Human Immunodeficiency Virus Type 1-Infected Individuals," *Journal of Virology* 71(5):3734-3741, May 1997.
- _____ O40 Moore, J.P. and D.D. Ho, "HIV-1 Neutralization: The Consequence of Viral Adaptation to Growth on Transformed T-Cells," *AIDS* 9(supp A):S117-S136, 1995.
- _____ O41 Mori, K., et al., "Quintuple Deglycosylation Mutant of Simian Immunodeficiency Virus SIVmac239 in Rhesus Macaques: Robust Primary Replication, Tightly Contained Chronic Infection, and Elicitation of Potent Immunity Against the Parental Wild-Type Strain," *Journal of Virology* 75(9):4023-4028, May 2001.
- _____ O42 Ohgimoto, S., et al., "Location-Specific, Unequal Contribution of the N Glycans in Simian Immunodeficiency Virus gp120 to Viral Infectivity and Removal of Multiple Glycans without Disturbing Infectivity, *Journal of Virology* 72(10):8365-8370, October 1998.
- _____ O43 Poss, M., et al., "Evolution of Envelope Sequences from the Genital Tract and Peripheral Blood of Women Infected with Clade A Human Immunodeficiency Virus Type 1," *Journal of Virology* 72(10):8240-8251, October 1998.
- _____ O44 Putney, S.D., et al., "HTLV-III/LAV-Neutralizing Antibodies to an *E.coli*-Produced Fragment of the Virus Envelope," *Science* 234:1392-1395, December 1986.

- _____ O45 Quinones-Koch, M.I., et al., "Role of N-Linked Glycans in a Human Immunodeficiency Virus Envelope Glycoprotein: Effects on Protein Function and the Neutralizing Antibody Response," *Journal of Virology* 76(9):4199-4211, May 2002.
- _____ O46 Reimann, K.A., "An *env* Gene Derived From a Primary Human Immunodeficiency Virus Type 1 Isolate Confers High In Vivo Replicative Capacity to a Chimeric Simian/Human Immunodeficiency Virus in Rhesus Monkeys," *Journal of Virology* 70(5):3198-3206, May 1996.
- _____ O47 Reimann, K.A., et al., "A Chimeric Simian/Human Immunodeficiency Virus Expressing a Primary Patient Human Immunodeficiency Virus Type 1 Isolate *env* Causes an AIDS-Like Disease After In Vivo Passage in Rhesus Monkeys," *Journal of Virology* 70(10):6922-6928, October 1996.
- _____ O48 Richman, D.D., et al., "Rapid Evolution of the Neutralizing Antibody Response to HIV Type 1 Infection," *Proceedings of the National Academy of Sciences* 100(7):4144-4149, April 2003.
- _____ O49 Rudensey, L.M., et al., "Changes in the Extracellular Envelope Glycoprotein of Variants That Evolve During the Course of Simian Immunodeficiency Virus SIVMne Infection Affect Neutralizing Antibody Recognition, Syncytium Formation, and Macrophage Tropism but not Replication, Cytopathicity, or CCR-5 Coreceptor Recognition," *Journal of Virology* 72(1):209-217, January 1998.
- _____ O50 Scanlon, C.N., et al., "The Broadly Neutralizing Anti-Human Immunodeficiency Virus Type 1 Antibody 2G12 Recognizes a Cluster of $\alpha 1 \rightarrow 2$ Mannose Residues on the Outer Face of gp120," *Journal of Virology* 76(14):7306-7321, July 2002.
- _____ O51 Shankarappa, R., et al., "Consistent Viral Evolutionary Changes Associated with the Progression of Human Immunodeficiency Virus Type 1 Infection," *Journal of Virology* 73(12):10489-10502, December 1999.
- _____ O52 Stamatatos, L., and C. Cheng-Mayer, "An Envelope Modification That Renders a Primary, Neutralization-Resistant Clade B Human Immunodeficiency Virus Type 1 Isolate Highly Susceptible to Neutralization by Sera From Other Clades," *Journal of Virology* 72(10):7840-7845, October 1998.
- _____ O53 Stamatatos, L., et al., "Generation and Structural Analysis of Soluble Oligomeric gp140 Envelope Proteins Derived From Neutralization-Resistant and Neutralization-Susceptible Primary HIV Type 1 Isolates," *AIDS Research and Human Retroviruses* 16(10):981-994, 2000.

- _____ O54 Stamatos, N.M., et al., "Neutralizing Antibodies From the Sera of Human Immunodeficiency Virus Type 1-Infected Individuals Bind to Monomeric gp120 and Oligomeric gp140," *Journal of Virology* 72(12):9656-9667, December 1998.
- _____ O55 Steimer, K.S., et al., "Neutralization of Divergent HIV-1 Isolates by Conformation-Dependent Human Antibodies to Gp120," *Science* 254(5028):105-108, October 1991.
- _____ O56 Sullivan, N., et al., "CD4-Induced Conformational Changes in the Human Immunodeficiency Virus Type 1 gp120 Glycoprotein: Consequences for Virus Entry and Neutralization," *Journal of Virology* 72(6):4694-4703, June 1998.
- _____ O57 Sullivan, N., et al., "Effect of Amino Acid Changes in the V1/V2 Region of the Human Immunodeficiency Virus Type 1 gp120 Glycoprotein on Subunit Association, Syncytium Formation, and Recognition by a Neutralizing Antibody," *Journal of Virology* 67(6):3674-3679, June 1993.
- _____ O58 Wang, F.-X., et al., "Emergence of Autologous Neutralization-Resistant Variants From Preexisting Human Immunodeficiency Virus (HIV) Quasi Species During Virus Rebound in HIV Type 1-Infected Patients Undergoing Highly Active Antiretroviral Therapy," *Journal of Infectious Diseases* 185:608-617, 2002.
- _____ O59 Wang, L.-X., et al., "Binding of High-Mannose-Type Oligosaccharides and Synthetic Oligomannose Clusters to Human Antibody 2G12," *Chemistry & Biology* 11(1):127-134, January 2004.
- _____ O60 Wei, X., et al., "Emergence of Resistant Human Immunodeficiency Virus Type 1 in Patients Receiving Fusion Inhibitor (T-20) Monotherapy," *Antimicrobial Agents and Chemotherapy* 46(6):1896-1905, June 2002
- _____ O61 Wei, X., et al., "Antibody Neutralization and Escape by HIV-1," *Nature* 422:307-312, March 2003.
- _____ O62 Willey, R.L., et al., "Differential Glycosylation, Virion Incorporation, and Sensitivity to Neutralizing Antibodies of Human Immunodeficiency Virus Type 1 Envelope Produced From Infected Primary T-Lymphocyte and Macrophage Cultures," *Journal of Virology* 70(9):6431-6436, September 1966.
- _____ O63 Wolinsky, S.M., et al., "Adaptive Evolution of Human Immunodeficiency Virus-Type 1 During the Natural Course of Infection," *Science* 272(5261):537-542, April 1996.
- _____ O64 Wyatt, R., and J. Sodroski, "The HIV-1 Envelope Glycoproteins: Fusogens, Antigens, and Immunogens," *Science* 280:1884-1888, June 1998.

- _____ O65 Wyatt, R., et al., "Involvement of the V1/V2 Variable Loop Structure in the Exposure of Human Immunodeficiency Virus Type 1 gp120 Epitopes Induced by Receptor Binding," *Journal of Virology* 69(9):5723-5733, September 1995.
- _____ O66 Wyatt, R., et al., "The Antigenic Structure of the HIV gp120 Envelope Glycoprotein," *Nature* 393:705-711, June 1998.
- _____ O67 Zhang, M., et al., "Tracking Global Patterns of N-Linked Glycosylation Site Variation in Highly Variable Viral Glycoproteins: HIV, SIV, and HCV Envelopes and Influenza Hemagglutinin," *Glycobiology* 14(12):1229-1246, June 2004.
- _____ O68 Zhu, X., "Mass Spectrometric Characterization of the Glycosylation Pattern of HIV-gp120 Expressed in CHO Cells," *Biochemistry* 39:11194-11204, 2000.
- _____ O69 Zolla-Pazner, S., "Identifying Epitopes of HIV-1 That Induce Protective Antibodies," *Nature Reviews* 4:199-210, March 2004.
- _____ O70 Zwick, M.B., et al., "A Novel Human Antibody Against Human Immunodeficiency Virus Type 1 gp120 Is V1, V2, and V3 Loop Dependent and Helps Delimit the Epitope of the Broadly Neutralizing Antibody Immunoglobulin G1 b12," *Journal of Virology* 77(12):6965-6978, June 2003.

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Seattle Biomedical Research Institute
306 Westlake Ave N Suite 500
Seattle, Washington 98109-5219
206.256.7200